AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Figure 1. This sheet, which includes Figures 1 and 2, replaces the original sheet including Figures 1 and 2.

Attachment: Replacement Sheet

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-14 are pending in this application. Claims 7 and 9 are amended and no claims have been cancelled. Claim 1 is the sole independent claim. Claims 7-10 and 14 have been withdrawn from consideration.

Applicants respectfully note that the present action does not indicate that the claim to foreign priority under 35 U.S.C. §119 has been acknowledged or that certified copies of all priority documents have been received by the U.S.P.T.O. Applicants respectfully request that the Examiner's next communication include an indication as to the claim to foreign priority under 35 U.S.C. §119 and an acknowledgement of receipt of the certified copies of all priority documents.

Drawings

The drawings have been objected to under 37 C.F.R. § 1.83(a) because they allegedly fail to show detail as described in the specification. Applicants respectfully traverse this objection. Applicants have amended the specification in accordance with Examiner's suggestion. Therefore, withdrawal of the objection to the drawings is respectfully requested.

Specification

The disclosure has been objected to for the following informalities: the arrangement of the specification does [not] follow the suggested guidelines, in particular there is no Brief Description of Drawings or Cross-Reference to Related Applications. Applicants have amended the specification in accordance with Examiner's

suggestion. Therefore, withdrawal of the objection to the specification is respectfully requested.

Rejections under 35 U.S.C. § 112

Claims 7 and 9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended claims 7 and 9 in accordance with Examiner's suggestions.

The Applicants, therefore, respectfully request that the rejection to Claims 7 and 9 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejections under 35 U.S.C. § 103

Antananvich in view of Okazaki and Wang

Claims 1-11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,372,244 to Antananvich et al. (hereinafter "Antananvich") in view of Adv. Engineering Materials, 2000, p. 278-281 by Okazaki and U.S. Publication No. 2003/0153981 to Wang et al. (hereinafter "Wang"). Applicants respectfully traverse this rejection for the reasons detailed below.

Applicants agree with the Examiner that Antanavich does not disclose that the semipermeable barrier has a surface coating of a bioactive metal as recited in claim 1, but in clear contrast, the alginate coat of Antanavich has a further alginate overcoat. The outstanding Office Action on page 8, lines 4-5, acknowledges that Antananvich fails to disclose a surface coating of a bioactive metal and relies on the teachings of Okazaki and Wang for this feature of claim 1.

In addition to the above-identified deficiency of Antanavich, Applicants respectfully submit that both Okazaki and Wang teach away from the bioartifical implant recited in claim 1.

First, Okazaki tests a new titanium alloy used for hip replacements (page 279, left column, first paragraph; page 279, right column, third paragraph). The tested alloy is used for a homogenous titanium alloy implant and does not contain any surface coating. However, Okazaki mentions that another titanium alloy hip implant has been surface coated with titanium plasma-spray in combination with a coating of apatite-wollastonite-containing glass-ceramic in order to improve the rate of stable bone contact of the hip implant. Applicants note that plasma-spraying is a method of thermal spraying in which the material to be deposited is fed into a high temperature plasma torch (a temperature generally in the order of several thousand Kelvin). The material melts and is propelled towards the material, where the molten material rapidly solidifies and forms a deposit. The deposition technique disclosed by Okazaki works well if the substrate is a solid titanium body as is the case in the hip implant.

However, Applicants respectfully submit that the disclosed coating technique of Okazaki cannot be used to coat a semipermeable membrane of a bioartificial implant as recited in claim 1, and in addition, teaches away from the bioactive metal coating in the bioartificial implant of claim 1 because the melted high temperature titanium (alloy) drops would decompose the semipermeable barrier, thereby effectively destroying the sensitive substrate structure. As such, the titanium plasma-spray coating technique merely mentioned but not disclosed in detail in Okazaki can only be used for solid metal substrates and not semipermeable barrier substrates as recited in claim 1. Therefore, Applicants respectfully submit that Okazaki teaches away from the bioartificial implant of claim 1.

Further, Wang discloses the production of a porous metal scaffold for orthopaedic implants (paragraphs 16, 17, 84). The scaffold is produced by providing a polymer foam and forming a skin of titanium on the polymer foam by low temperature arc vapour deposition (paragraphs 22-23, 41-42, 90, 102). The resulting structure is heated at a high temperature to decompose the polymer foam and form a green foam (paragraphs 24, 43, 92, 104, 106). The sensitive green foam is pre-sintered at about 1315 °C (paragraphs 44, 93, 110) and then thickened. The thickening of the green foam is achieved by adding a binder solution and then depositing titanium particles (paragraphs 25, 35-37, 45, 93, 111-112, 114). The particles are bonded to the green foam by sintering at about 1425-1530 °C to form the porous metal scaffold (paragraphs 46, 94, 115). The application of titanium particles to the green foam reduces the pore size of the green foam (paragraphs 25, 27, 53, 93, 114). Wang thus discloses a technique for forming a porous metal scaffold for orthopaedic implants which improves the in-growth of bone and promotes the initial press-fit stability (paragraphs 16, 88).

However, Applicants respectfully submit that the disclosed coating technique of Wang cannot be used to coat a semipermeable membrane of a bioartificial implant as recited in claim 1, and in addition, teaches away from the bioactive metal coating in the bioartificial implant of claim 1 because the techniques disclosed by Wang are only possible when using a metal substrate, such as titanium. The deposition of titanium particles to the titanium foam requires a high temperature sintering in order to effectively attach the titanium particles to the titanium foam structure. The required sintering temperatures of over 1400 °C cannot be used in connection with a bioartificial implant as recited in claim 1 having a sensitive semipermeable barrier as the barrier would decompose at this high temperature. Additionally, the titanium particle deposition as disclosed by Wang will reduce the pore size of the titanium green

foam, and thus, the particle deposition technique of Wang will affect the semipermeability of the semipermeable barrier.

Finally, Wang also discloses coating an original polymer form with titanium by low temperature arc vapour deposition. However, this deposition technique as disclosed by Wang will affect the pore size and the porosity of the polymer foam as the titanium creates a layer on all surfaces of the polymer foam (paragraphs 90, 103; Fig. 5). The reason for this negative effect of the titanium on the semipermeability is that the titanium coats both the internal and external surfaces of the polymer web. Therefore, Applicants respectfully submit that Wang also teaches away from the bioartificial implant of claim 1.

With respect to the proposed combination of Antanavich, Okazaki and Wang, Applicants respectfully submit that the combination is improper for at least the following reasons.

Antanavich discloses a bioartificial implant with an alginate-based semipermeable membrane. Okazaki mentions surface coating of solid titanium alloy implants, which are fundamentally different from the bioartificial implant of Anatanavich. The coating technique disclosed by Okazaki, i.e. plasma spray, cannot be used together with the bioartificial implant of Antanavich as it would effectively destroy the sensitive alginate membrane. One skilled in the art therefore realizes that the surface coating of titanium mentioned by Okazaki, and which achieves stable bone contact, is incompatible with the bioartificial implant of Antanavich. Additionally, the coating technique is not only incompatible with Antanavich, one skilled in the art further sees no use of having improved stable bone contact with the bioartificial implant of Antanavich. In clear contrast, the bioartificial implant should provide

sufficient passive diffusion of nutrients over the semipermeable barrier, which has nothing to do with the advantage of stable bone contact as taught by Okazaki.

The metal particle deposition technique of Wang is further not possible to apply to a bioartificial implant comprising semipermeable membranes as disclosed by Antanavich. In clear contrast, the high sintering temperature that is needed in order to bind the particles to the substrate would effectively destroy the alginate membrane of Antanavich. Furthermore, the deposition technique of Wang reduces the pore size, which would negatively affect the passive transport of nutrients over the semipermeable barrier of Antanavich. Therefore, not only is Wang not applicable to bioartificial implants comprising semipermeable barriers as recited in claim 1 and disclosed by Antanavich, one skilled in the art would not even attempt the technique of Wang, if it indeed would have been physically possible, because the pores of the semipermeable barrier would fill up and thereby prevent or at least substantially hinder the transport of substances over the semipermeable barrier.

Additionally, the technical effects achieved by the titanium coating according to Wang, i.e. improved bone in-growth, promoted initial press-fit stability and greater frictional interference to bone, have no connection with or provide any advantageous effects to the bioartificial implant of Antanavich. As such, Applicants respectfully submit that the techniques disclosed by both Okazaki and Wang are incompatible with the bioartificial implant of Antanavich, and therefore, cannot render claim 1 obvious.

The Applicants, therefore, respectfully request that the rejection to Claims 1-11 under 35 U.S.C. § 103(a) be withdrawn.

Claims 2-11, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 1 and all claims dependent thereon.

Brauker in view of Okazaki and Wang

Claims 1-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,782,912 to Brauker et al. (hereinafter "Brauker") in view of Okazaki and Wang. Applicants respectfully traverse this rejection for the reasons detailed below.

Applicants agree with the Examiner that Brauker does not disclose that the semipermeable barrier has a surface coating of a bioactive metal as recited in claim 1, but in clear contrast, Brauker at most speculates that a biocompatible metal can be used as semipermeable membrane. The outstanding Office Action on page 10, lines 7-8, acknowledges that Brauker fails to disclose a surface coating of a bioactive metal and relies on the teachings of Okazaki and Wang for this feature of claim 1.

In addition to the above-identified deficiency of Brauker, Applicants respectfully submit that Brauker, Okazaki and Wang teach away from the method recited in claim 1.

Applicants respectfully submit that there is no indication in Brauker that guides one skilled in the art towards applying a surface coating of a bioactive metal to a semipermeable barrier. On the contrary, Brauker guides one skilled in the art towards usage of a sandwich membrane structure, which is a fundamentally different from the structure of the bioartificial implant as recited in claim 1.

The bioartificial implant of Brauker with its semipermeable membrane is as incompatible with the coating techniques of Okazaki and Wang as Antanavich. The above presented discussion, according to which one skilled in the art would have realized that Okazaki and Wang cannot be applied to the bioartificial implant of

Antanavich, also applies to the bioartificial implant of Brauker. The only major difference between Antanavich and Brauker is that the semipermeable barrier of Antanavich is made of alginate polymers, whereas Brauker discloses materials listed in Tables 1-3. However, Applicants submit that none of these materials can withstand the high temperatures required by Okazaki and Wang. Furthermore, the effects achieved by the titanium coating according to Okazaki and Wang will not provide any additional advantage to the bioartificial implant of Brauker.

As such, Applicants respectfully submit that the techniques disclosed by both Okazaki and Wang are incompatible with the bioartificial implant of Brauker, and therefore, cannot render claim 1 obvious.

The Applicants, therefore, respectfully request that the rejection to Claims 1-13 under 35 U.S.C. § 103(a) be withdrawn.

Claims 2-13, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 1 and all claims dependent thereon.

CONCLUSION

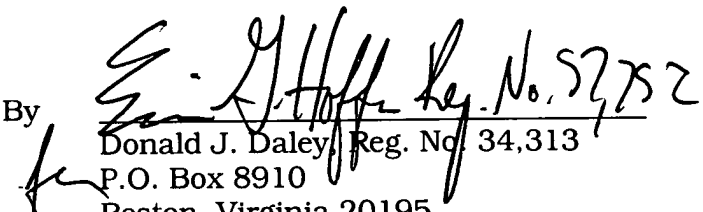
In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By 
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